

REMARKS

Claim Rejections – 35 U.S.C. § 101

Claims 1, 3, 5, 7, 8, 10-12, and 14-23 stand rejected under 35 U.S.C. § 101 regarding statutory subject matter. Independent claim 1 and dependent claim 16 have been amended for the sake of clarity and contain no new matter. Applicants respectfully assert that claims 1, 3, 5, 7, 8, 10-12, and 14-23 are directed to statutory subject matter, and request that the § 101 rejections to these claims be withdrawn.

Claim Rejections – 35 U.S.C. § 112

Claim 3 has been rejected under 35 U.S.C. § 112, second paragraph as indefinite. Claim 3 has been amended for the sake of clarity and contains no new matter. Applicants respectfully assert that amended claim 3 is not indefinite, and as such, request that this rejection to claim 3 be withdrawn.

Claim Rejections – 35 U.S.C. § 103

Claims 1, 3, 5, 7, 8, 10-12, and 14-15 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,403,335 (“*Loomas*”) in view of U.S. Patent No. 5,308,355 (“*Dybbs*”) and further in view of U.S. Patent No. 5,133,726 (“*Ruiz*”).

Claims 1, 3, 7, 8, and 14-15

Independent claim 1 recites, in part:

“An automated mechanical device to separate the epithelial layer of a cornea from the cornea ... comprising:

a separator, ...

an oscillation device that provides motion and vibration to the separator, wherein the separator oscillates with frequency ranging from about 10Hz to about 10KHz; and

rotating gears ... where rotation to the gears is provided by said oscillating device...”

The proposed combination of *Loomas*, *Dybbs*, and *Ruiz* fails to teach or suggest all of the features of independent claim 1.

First, the proposed combination fails to teach an oscillation device that provides motion and vibration to the separator, wherein the separator oscillates with frequency ranging from about 10Hz to about 10KHz. The Office Action correctly concedes that “*Loomas* is silent regarding the separator oscillating with a frequency ranging from about 10Hz to about 10KHz.” (Office Action, p. 3). *Dybbs* and *Ruiz* fail to fill in the gaps.

The corneal surgical instrument described in *Dybbs* has a cutting blade, and additionally has two probes located near the cutting blade. (*Dybbs*, col. 2, lines 5-11). The probes in *Dybbs* monitor the position of the knife and the depth of the cutting blade by measuring the thickness of the cornea. (*Dybbs*, col. 2, lines 11-17). This measurement is done by generating a 20 MHz beam “directed along the axis of the contact head” and measuring its echo response. (*Dybbs*, col. 5, lines 33-42). “The difference in time of [a first echo corresponding to the anterior corneal surface and a second echo corresponding to the posterior corneal surface] received back at the transducer is a measure of the corneal thickness.” (*Dybbs*, col. 5, lines 39-44). “By repeatedly pulsing the transducer and detecting echoes, the thickness of the cornea may be continuously monitored and reported by depth measuring circuitry to the computer.” (*Dybbs*, col. 5, lines 48-52).

However, this monitoring beam is not an oscillation device that provides motion and vibration to a separator. As such, *Dybbs* fails to teach or suggest those features not taught by *Loomas*.

Additionally, *Ruiz* does not teach or suggest these features of claim 1. *Ruiz* is directed to an automatic corneal shaper for performing automatic lamellar corneal resections. (*Ruiz* Abstract). However, *Ruiz* fails to teach an oscillation device that provides motion and vibration to the separator, where the separator oscillates with frequency ranging from about 10Hz to about 10KHz.

For at least this reason, Applicants respectfully assert that the proposed combination fails to teach all of the features of independent claim 1.

Second, the proposed combination fails to teach rotating gears where rotation to the gears is provided by the oscillating device. The Office Action correctly admits that “Loomas is silent regarding ... rotating gears which [sic] placed on the separator support.” (Office Action, p. 3). *Dybbs* and *Ruiz* fail to fill in the gaps.

As shown above, *Dybbs* fails to teach an oscillating device. Further, *Dybbs* is silent with respect to rotating gears.

Ruiz teaches “pinions 33 and 34, pinion 33 being engaged with pinion 32 and being larger in diameter, while pinion 34 being engaged with pinion 33 and being in turn larger in diameter.” (*Ruiz*, col. 4, lines 1-5). The pinions are rotated by pinion-shaft 31, which “is connected at teach end to a pinion 32” and engages the threaded area 22 of the shaft end 28. (*Ruiz*, col. 3, line 63 – col. 4, line 1; Fig 1). However, the pinion-shaft 31 is not an oscillating device that provides motion and vibration to the separator, where the separator oscillates with frequency ranging from about 10Hz to about 10KHz. As such, *Ruiz* fails to teach or suggest rotating gears where rotation to the gears is provided by the oscillating device.

Applicants respectfully assert that, for this additional reason, the proposed combination fails to teach all of the features of independent claim 1. Because not all of the features are taught, Applicants respectfully request that the § 103 rejection to this claim be withdrawn. Additionally, claims 3, 7, 8, and 14-15 depend from independent claim 1, and therefore, Applicants respectfully request that the § 103 rejections to these claims also be withdrawn.

Claim 5

Claim 5 depends from independent claim 1, and is therefore allowable for all of the reasons previously presented. Additionally, claim 5 includes the feature “where a travel of the separator is controlled to produce an epithelial disk hinged to the border of separation.”

The proposed combination of *Loomas*, *Dybbs*, and *Ruiz* fails to teach this additional feature of claim 5. *Loomas* teaches a dissector which is rotated around an eye to produce a channel (see, e.g., *Loomas*, col. 7, lines 49-56), but fails to

teach the travel of a separator that produces an epithelial disk hinged to the border of separation. *Dybbs* teaches making “a series of radial incisions ... in the cornea peripherally around the central corneal zone” in order to flatten the cornea (see, e.g., *Dybbs*, col. 1, lines 18-24), but also fails to teach the travel of a separator that produces an epithelial disk hinged to the border of separation. *Ruiz* teaches a device for performing a resectioning of the cornea of an eye (see, e.g., *Ruiz*, col. 1, lines 5-11), but is silent with respect to the travel of a separator that produces an epithelial disk hinged to the border of separation.

As such, Applicants respectfully assert that the proposed combination of references fails to teach or suggest the above-described feature of claim 5. For this additional reason, Applicants respectfully request that the § 103 rejection to this claim be withdrawn.

Claims 10 and 11

Applicants preliminarily note that the Office Action contradicts itself. The Office Action initially states that claims 10 and 11 stand rejected over *Loomas* in view of *Dybbs* and further in view of *Ruiz*. (Office Action, p. 3). However, the Office Action later states that “[r]egarding claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Loomas* in view of *Urich*.” (Office Action, p. 4). The Office Action adds that “*Loomas* discloses the invention substantially as claimed.” (Office Action, p. 4).

Claims 10 and 11 depend from independent claim 1, and thus include an oscillation device that provides motion and vibration to the separator, wherein the separator oscillates with frequency ranging from about 10Hz to about 10KHz, and rotating gears where rotation to the gears is provided by said oscillating device. As noted above, the proposed combination of *Loomas*, *Dybbs*, and *Ruiz* fails to teach these features. *Urich* fails to fill in the gaps.

Urich is directed to a disposable surgical ultrasonic transducer with a disposable piezoelectric driver. (*Urich* Abstract). A surgical tip or blade is attached to one end of a horn, while the piezoelectric driver is attached to the other end.

(*Urich*, col. 1, lines 58-61). The driver contains a transducer that creates a vibratory movement of the horn and tip. (*Urich*, col. 1, lines 62-65).

However, the piezoelectric driver in *Urich* does not disclose or suggest an oscillation device that provides motion and vibration to the separator, wherein the separator oscillates with frequency ranging from about 10Hz to about 10KHz. Additionally, the piezoelectric driver in *Urich* fails to teach or suggest rotating gears where rotation to the gears is provided by said oscillating device.

For at least these reasons, the cited references fail to teach, either individually or in combination, all of the features of claims 10 and 11. As such, Applicants respectfully request the withdrawal of the § 103 rejections to these claims.

Claim 12

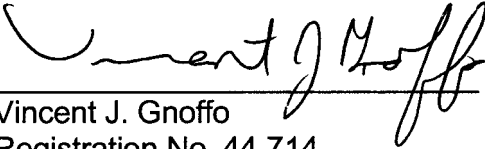
Claim 12 depends from independent claim 1, and is therefore allowable for all of the reasons previously presented. Additionally, claim 12 includes the feature “where the separator oscillation is provided by external rotating or vibrating wires.”

The proposed combination of *Loomas*, *Dybbs*, and *Ruiz* fails to teach this additional feature. As correctly conceded by the Office Action, *Loomas* is silent with respect to separator oscillations. (Office Action, p. 3). As shown above, *Dybbs* fails to teach or suggest an oscillating device. Also as shown above, *Ruiz* fails to teach or suggest the oscillation device as claimed. Further, each reference fails to suggest providing any sort of oscillation by external rotating or vibrating wires.

For this additional reason, Applicants respectfully assert that the proposed combination fails to teach or suggest all of the features of claim 12, and respectfully request the rejection to this claim be withdrawn.

Applicants respectfully request entry of this Amendment and allowance of this application. The Examiner is invited to contact the undersigned attorney for the Applicants via telephone if such communication would expedite this application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Vincent J. Gnoffo", written over a horizontal line.

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